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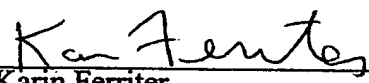
Scott B. Markow
Fish & Richardson
1425 K Street, NW
11th Floor
Washington DC 20005

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,650,787

Dear Mr. Markow:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,650,787 for a period of one year. A copy of the Federal Register Notice is also enclosed. The extension was published in the Federal Register on Monday, October 24, 2005. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.


Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: vapreotide acetate
FDA Docket No.:

UNITED STATES PATENT AND TRADEMARK OFFICE

In re H3 Pharma, Inc.
Request for Patent Term Extension
U.S. Patent No. 4,650,787

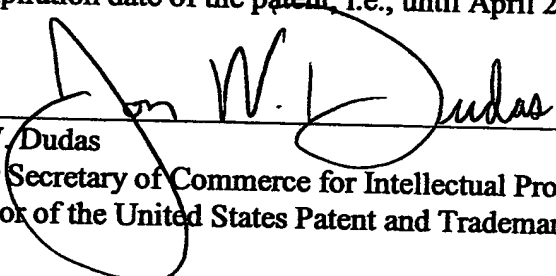
:
: **CERTIFICATE OF**
: **INTERIM EXTENSION**

On April 7, 2005, H3 Pharma, Inc., an agent of the Administrators of the Tulane Educational Fund of New Orleans, Louisiana, the patent owner, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 4,650,787. The patent claims the active ingredient vapreotide acetate in the human drug product Sanvar®, and a method of use of said product. The application indicates that a New Drug Application for Sanvar® (vapreotide acetate) has been filed and is currently undergoing regulatory review before the Food and Drug Administration for permission to market or use the product commercially.

Review of the application indicates that except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Since the regulatory review period extended beyond the expiration date of the patent April 25, 2005, interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 4,650,787 is granted for a period of one year from the expiration date of the patent, i.e., until April 25, 2006.

10/17/05
Date


Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

United States Patent and Trademark Office

Grant of Interim Extension of the Term of U.S. Patent No. 4,650,787; vapreotide acetate

AGENCY: United States Patent and Trademark Office

ACTION: Notice of Interim Patent Term Extension

SUMMARY: The United States Patent and Trademark Office has issued a certificate under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 4,650,787.

FOR FURTHER INFORMATION CONTACT: Karin Ferriter by telephone at (571) 272-7744; by mail marked to her attention and addressed to Mail Stop Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7744, or by e-mail to Karin.Ferriter@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has

been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to a year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

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